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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,449	11/30/2001	Shamim M. Malik	50623.134	3441

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Squire, Sanders & Dempsey L.L.P.
Suite 300
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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06/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/997,449	Applicant(s) MALIK ET AL.	
	Examiner Melanie Tyson	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8-10,13 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8-10,13 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 March 2008 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1, 4-6, 8-10, 13, and 31 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 4-6, 8-10, 13, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (6,083,257) in view of Ecer et al. (4,486,247), or in the alternative, over Taylor et al. in view of Ecer et al. and Kamath et al. (6,335,029).

Taylor discloses a stent (see entire document) comprising a metallic stent body formed of a stainless steel alloy (for example, see column 5, lines 51-56 and lines 62-63) having a polymer film (for example see column 3, lines 63-67). The limitation “plasma-polymerized” is being treated as a product by process limitation, in that “plasma-polymerized” refers to the process of depositing the polymer film layer to the stent and not to the final product created. As set forth in MPEP 2113, “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985). Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, a stent as described above wherein the polymer film layer is plasma-polymerized over the stent body is directed to the method of making the stent and not to the final product made. In the alternative Kamath teaches a plasma polymerization process. Kamath teaches that this process allows covalent bonding between layers, thus subsequently offers a stronger adhesion (for example, see column 8, lines 37-44). It is

well within the general knowledge of one having ordinary skill in the art to use a known technique to improve similar devices in the same way. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to deposit Taylor's polymer film layer by a plasma polymerization process as taught by Kamath et al. Doing so would enhance the bond between the stent body and the polymer film.

Taylor fails to disclose the stent body comprises a carbon deposit. However, it is well known that stainless steel materials containing carbon implanted within the surface as claimed enhances the strength and hardness of the stainless steel surface. Ecer discloses a stainless steel base material being modified by having carbon implanted within the surface of the stainless steel base material in order to enhance wear resistance (see detailed description of the Ecer et al. patent). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Taylor's stent body with a carbon deposit as taught by Ecer. Doing so would improve the stent's wear resistance.

With further respect to claims 4-6, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the film layer with the materials claimed, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

With further respect to claim 10, it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat the stent with a polymeric layer comprising a therapeutic substance, since it is well known in the art to coat stents with drugs and agents in order to provide further treatment to the placement site. In the alternative, Kamath teaches forming a polymeric layer comprising a therapeutic substance formed on the plasma-polymerized film layer (see detailed description). It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device ready for improvement to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a polymeric layer comprising a therapeutic substance on the polymer film layer as taught by Kamath. Doing so would promote further healing to the treatment site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
June 3, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773